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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,660	10/09/2001	Christopher R. O'Keefe	BSC-202	6343

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/973,660

Applicant(s)

O'KEEFE ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 14-36 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 30-36 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 14-17 and 29 is/are allowed.
- 6) ☒ Claim(s) 18, 21, 25, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 22-24 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 10/01, 1/03, 3/03
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18, 21, 25 and 28 are rejected under 35 U.S.C. § 102(e) as being anticipated by Migachyov (US 6,183,413 B1).

Regarding claim 18, Migachyov teaches a valve (10) for preventing reflux of fluids comprising:

a tube (12) defining a lumen (14, 20, 22) having a first end (16) and a second end (18), and a socket (20);

a shaft (31) at least partially disposed in the socket (22); and

a stopper (34) attached to the shaft (31) that occludes the lumen (14, 20, 22)(within the socket) when exposed to retrograde pressure (or simply too little forward pressure to counteract the spring (38) bias)(see figures 1 and 3, below).

Regarding the preambles limitation of the valve preventing reflux in a ureteral stent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use,

then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant invention, applicants recite no structure which distinguishes the claimed invention from a biased closed spring valve used in a conventional urethral catheter.

Additionally, Migachyov teaches a device that inherently prevents fluid reflux to any portion of the urinary path which lies upstream of the valve, including the bladder, ureter and kidneys.

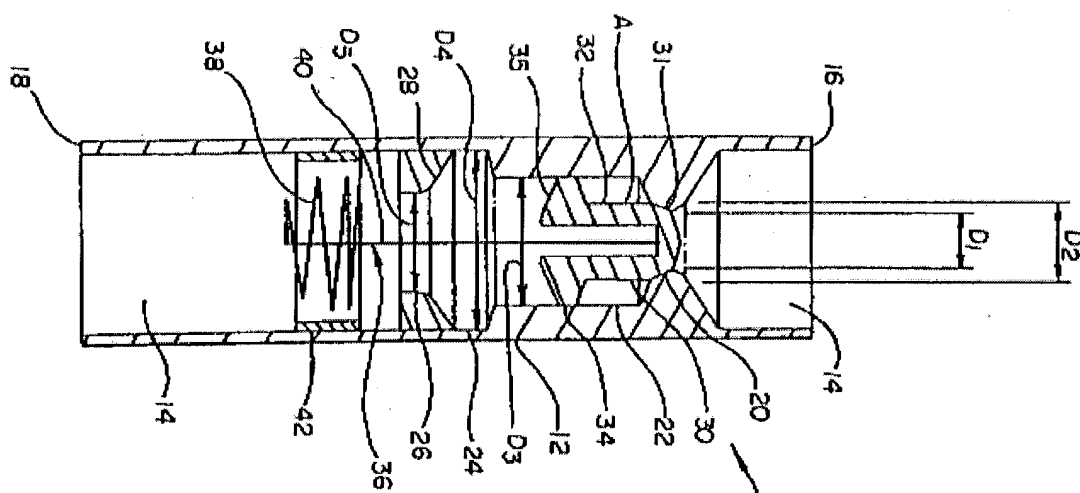


Fig. 1



Regarding claim 21, Migachyov teach a shaft (31) which is axially translatable in the socket (22).

Regarding claim 25, Migachyov teach a stopper (34) comprising a substantially circular surface and a shaft (31) attached to the stopper (34) at the center of the circular surface (see figures 1 and 3). Note the tube interior is substantially cylindrical and the stopper is circular in order to conform with the interior shape.

Regarding claim 28, Migachyov teaches a stopper (34) which comprises a wedge shaped section. Applicants are directed to figures 1 and 3, which shows the stopper cross section which shows a wedge on opposite sides of the stopper (31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3761

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 27 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Migachyov.

Migachyov teach the claimed invention except for a stopper (31) having a hemispherical surface instead of a slightly conical surface (see figure 3).

Mere changes in shape are generally not sufficient to distinguish an invention over the prior art unless an unexpected result is achieved. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). In the present case, the conical surface of the stopper of Migachyov functions in the same manner as that of the hemispherical stopper of the instant invention. Both designs utilize a similar shape to provide a secure abutment against their respective lumen to allow or block fluid flow, making them mechanical equivalents.

#### ***Allowable Subject Matter***

Claims 1-11, 14-17 and 29 are allowed

Art Unit: 3761

Claims 19, 20, 22-24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 1-11, 14-17 and 29, the most relevant art of record are Finney (US 4,307,723) and Migachyov. Finney teaches a ureteral stent that may include a valved terminus in to be inserted at the bladder end in order to prevent reflux, which addresses the same problem that the instant invention purports to solve (column 5, lines 34-44). Magachyov teaches a valve for bladder control devices that is structurally similar to the claimed valve structure. However, there is no suggestion by either reference to combine them so the a ureteral stent having a first lumen, and a valve comprising a second lumen attached at the end of the first lumen, the valve including a shaft within a socket, and a stopper attached to the shaft, the stopper blocking the second lumen when exposed to reflux pressure.

Regarding claims 19 and 20, the closet art of record, Migachyov, teaches a shaft which is movable within a socket and thus fails to teach a shaft fixed to the socket.

Regarding claim 22, Migachyov fails to teach a shaft and socket tapered inwardly to prevent removal of the shaft from the socket.

Regarding claim 23, Migachyov teaches a spring biasing means (38), but does not teach that the spring is located within the socket (22).

Regarding claim 24, Migachyov fails to teach an additional lumen disposed about the periphery of the socket.

Regarding claim 18, Migachyov fails to teach a lip upon the stopper.

Art Unit: 3761


*Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Bogart  
17 November 2004

  
Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700